

Chapter 12

Safety and Side Effects of Acupuncture and Moxibustion as a Therapy for Cancer

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Abstract Acupuncture and moxibustion are safe treatments if implemented by trained, regulated practitioners with knowledge of human anatomy and potential adverse effects. Major (life-threatening) adverse effects are quite rare. They include pneumothorax, major hemorrhage, infection, septicemia, perforation of the brain stem, spread of blood-borne infections (such as hepatitis and human immunodeficiency virus), vascular damage, perichondritis, organ perforation, cardiac tamponade, bacterial endocarditis, arrhythmias, burns, scarring and allergic reactions. Instant recognition of these complications is required for successful emergent treatment, which may be life-saving. Minor adverse effects include mild skin reactions, dermatitis, local pain, bruising, syncope, and drowsiness. These are usually not problematic unless allowed to cause complications, such as trauma from syncope. Thorough history taking and attention to high practice standards will reduce the complication rate. This chapter covers well-documented adverse effects of acupuncture and provides guidance to avoid complications. In addition, it suggests guidelines for suspecting and dealing with acute emergencies. Cancer patients can be more susceptible to complications such as infection and bleeding. Moxibustion will also be examined, since it is often used as an integral part of cancer treatment in the East. It is important that the acupuncturist works closely with the oncologist to ensure appropriate application of acupuncture/moxibustion and to reduce the incidence of complications and ensure their timely management when they do occur. Risk factors for complications include: inadequate training, bleeding disorders, immunocompromised state, asthma, cachexia, diabetes, open wounds, cardiac valve abnormalities and vasovagal sensitivity. There is evidence that increased training and awareness of potential adverse effects will reduce the incidence of adverse effects. Informed patient consent is important. Hospital and clinic practice guidelines and certification of staff will ensure that practice is as safe as possible.

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12.1 Introduction

12.1.1 Acupuncture

In Traditional Chinese Medicine, acupuncture and moxibustion are integral therapies for the supportive care of cancer patients. They are used together with Chinese medicinal herbs to optimize health and to stabilize or cure the cancer. In Western medicine, acupuncture is mainly recognized for symptom control and alleviating the adverse effects of both the cancer and the cytotoxic treatments. Its utility has been established for specific indications using new data accumulated from clinical trials (Sagar 2008). Systematic reviews for specific indications are emerging and contributing to practice guidelines. For example, the role of acupuncture (or electrical stimulation of acupoints) to treat radiation-induced xerostomia has been critically reviewed (O'Sullivan and Higginson 2010). Although randomized controlled trials of acupuncture are methodologically challenging, they remain the capstone for clinical evidence in Western cancer clinics.

Since acupuncture is an invasive procedure, major concerns as to its safety were raised by Western physicians (Ernst and White 1997). In addition, their skepticism that it had any physical effect beyond placebo led to an initial focus on its potential to do harm. This was well-founded, since there were early reports of major adverse effects, such as the blood-borne transmission of hepatitis, septicemia due to an infected puncture site, and pneumothorax. This led to the eventual establishment of the regulation of acupuncture needles and the establishment of professional standards. For example, early Western acupuncturists would use a personal set of needles that would be autoclaved (with variable effectiveness) between patients. Currently, health regulatory bodies, such as the US Food and Drug Administration (FDA) only allow factory sterilized disposable needles (and these must meet acceptable manufacturing standards). The FDA recognizes and regulates the acupuncture needle as a Class II medical device. The prevention of the spread of infection was bolstered by Western acupuncture training that placed major emphasis on preventing infection through cleaning the skin and using disposable sterile needles. In addition, some contraindications and cautions were taught, such as avoiding lymphoedematous limbs, patients with cardiac valve abnormalities, dermatitis, etc. The new Western acupuncture schools (such as the Acupuncture Foundation of Canada) placed particular emphasis on the knowledge of human anatomy and prior medical training. These concerns were reinforced by new diagnostic imaging techniques that demonstrated the variability in dermal depth, organ positions, and aberrant foramina between different patients (Stark 1985, Chen et al. 2008). Reports of pneumothorax and pithing of the brain stem reduced the credibility of acupuncture. Migrating acupuncture needles were occasionally discovered on imaging and at surgery. However, it should be emphasized that these major adverse effects are currently rare owing to improved training and regulation of acupuncturists that has led to caution when using the riskier acupuncture points. Correct acupuncture technique is mandatory at certain sites, such as placing

needles horizontally (rather than deep vertical penetration). Electrical current passed through the acupuncture needle could interfere with a pacemaker or internal defibrillator. Points near the device should be avoided. In addition, caution should be exercised in patients with a history of arrhythmias, especially electrical stimulation across the arms and chest (Fujiwara et al. 1980; Thompson and Cummings 2008).

In addition to adverse effects from errors of commission, inappropriate treatment with acupuncture results in errors of omission. It is important that acupuncturists realize the appropriateness of biomedicine and surgery in specific circumstances. This requires some training in general medicine and excellent communication between the acupuncturist and practitioner. In the West, the primary treatment of cancer would be biomedical, with acupuncture being used in a supportive role.

12.1.2 Moxibustion

Moxibustion is a traditional Chinese method that uses the heat generated by burning herbal preparations containing *Artemisia vulgaris* to stimulate acupuncture points. There are two types of moxibustion. Direct moxibustion is applied directly to the skin surface at an acupuncture point. In indirect moxibustion some insulating materials are placed between the moxa cone and the skin. Sometimes the acupuncture needle is heated with smoldering moxa attached to the head and shaft of the needle (World Health Organization 2007). Assuming that moxibustion has some action for cancer patients, possible mechanisms of action have been evaluated. Moxa may be absorbed at acupuncture points, as well as direct effects due to acupuncture point stimulation from heat. Mechanisms may be similar to acupuncture, including both fascial and neurological activity. Of course, in models of Asian medicine, its activity will be translated into the flow of Qi along meridians. Moxibustion does influence the multiple cortical, subcortical/limbic, and brainstem areas. This is partly mediated through opioid and monoaminergic neurotransmission (Napadow et al. 2005; Han 2003; Dhond 2007). Another possible mechanism includes an influence on the heat shock proteins and the function of immune cells. It has been shown that moxibustion can up-regulate heat shock protein and decreases the gastric injury and apoptosis of gastric mucosal cells (Yi et al. 2007; Pei 1995). Laboratory work suggests that moxibustion improves the function of immune cells. Moxibustion induces higher cellular immune function and increases the content of β -endorphin in the lymphocytes of the spleen in HAC cancer mice. Moxibustion may modulate immunity through a neuro-hormonal regulatory mechanism. Moxibustion also inhibits the growth of tumor and enhances cellular immune functions *via* cytokine production (IL-2 or IL-12) and the increase of natural killer cell activity in tumor-bearing mice (Qiu et al. 2004).

In cancer patients, moxibustion is reported to strengthen the mechanisms of host defense through a response to heat-induced local inflammation. It produces immunological responses that include increased numbers of lymphocytes. One study suggests it can help restore immune functions affected by radiation (Hau 1989). In a study of mice, moxibustion at Dazhui (GV14) inhibited the growth of tumors through

enhancing cellular immune functions, probably by improvement of the production of cytokines, such as IL-2, and the resulting increased activity of natural killer cells (Jian 1995).

The neurotransmitter, galanin is synthesized in response to moxibustion. It can regulate pain, spasms and neurological disorders such as depression and anxiety (Kashiba et al. 1992). In a laboratory study on rabbits, the equivalent to Zusanli (ST36) was treated with moxibustion, and it was shown that smooth muscle spontaneous bowel movements decreased (Jiqing et al. 1986), suggesting that neurotransmitters were involved. The antispasmodic effect is consistent with what is seen during the clinical treatment of stomach and intestinal spasms with relief of diarrhea.

One of the most frequently mentioned uses of moxibustion in the Chinese literature is to stimulate the immune system. It is not yet known whether moxibustion differs in its effects compared to acupuncture alone. In the elderly, moxa-heated acupuncture needles (using needles and moxa applied for 20 min and daily treatment for 10 days applied to ST36) improved the production of IL-2 (Su 2003). In the system of traditional Chinese medicine, spleen deficiency (a subcategory of Qi deficiency) syndrome is often associated with weakened immune functions. An assessment of the immunological effects of moxibustion in the success or failure rate of cancer treatments was conducted suggesting it was important in reducing symptoms (Huaisheng 1995).

None of the theories of moxibustion therapy are fully established. A systematic review of the effectiveness of moxibustion for supportive cancer care showed that it was only effective for reducing nausea and vomiting (Lee et al. 2010). The review was not limited to the English language literature. However, all studies have a high risk of bias, so effectively there is not enough evidence to draw any conclusion. Further, the role of moxibustion, in our experience, is controversial in most Western medical clinics, although used in traditional Asian clinics. However, experience from Asia suggests that it may have an important role to play with acupuncture, especially in reducing fatigue and pain, as well as improving immunity. Some clinics are restricted by fire regulations and the controversial mistaken identity with marijuana. In addition, the smoke can result in respiratory adverse effects for some patients. Smokeless moxa sticks or a heat lamp can be used as alternative methods for applying heat. When heat sources are used, extreme caution should prevent local skin burns. In some traditions, scarification and scarring with a moxa burn is used as part of the therapy. This is not recommended by these authors.

12.2 Adverse Effects of Acupuncture

Acupuncture is a very safe treatment with a low side effect profile when administered by a trained practitioner who is aware of contraindications and high-risk situations (White et al. 2001). In a study of 98,000 patients, only six reported major adverse events related to the acupuncture (Melchart et al. 2004). These included pneumothorax, vasovagal reaction, hypertensive crisis, an acute asthma attack, and exacerbation of depression. A follow up study of 6,400 patients reported 10%

adverse effects of which only 0.3% were serious (MacPherson et al. 2004). This did not prevent most patients seeking further acupuncture. A prospective study of 34,000 treatments by traditional acupuncturists (nearly 600 practitioners) reported no major life-threatening events, a 15% rate of minor events, and only a 0.3% rate of major events (MacPherson 2001). A prospective study from the Czech Republic surveyed 140,000 acupuncture treatments and found that 7% of patients felt faint and 0.28% actually fainted (Umlauf 1988). The incidence of pneumothorax was rare at only 1/70,000 treatments. In a large prospective study of 74,000 patients, there were approximately 7.5% adverse effects of which only 2% required treatment and this was mainly self administered by the patients themselves (Witt et al. 2011). Assuming there is evidence that the acupuncture treatment is effective for reducing symptoms, the adverse effect rate is less than many drugs that are indicated for supportive care. The relative therapeutic gain should be considered when prescribing treatment options. A systematic review on the safety of acupuncture showed a range of common adverse effects (Ernst and White 2001). In the nine studies reviewed, the most common adverse events found were needle pain (1–45%), tiredness (2–41%), and local bleeding (0.03–38%). The incidence of faintness and syncope ranged from 0 to 3.0%. Feelings of relaxation were reported by 86% of the patients. Pneumothorax was rare, occurring only twice in nearly a quarter of a million treatments.

Proper training in acupuncture and professional standards are essential for safety. An Australian study found that less than 1 year's training resulted in 2.07 adverse events per year; 37–48 months' training reduced this to 1.35 adverse events per year; and 49–60 months' training reduced this further to 0.92 adverse events per year (Bensoussan and Myers 1996).

Adverse effects shall be divided into major or life-threatening, and minor or non-life-threatening. Major adverse effects are relatively rare and include pneumothorax, organ or brain perforation, severe bleeding, systemic infection, and arrhythmia. With adequate training and appropriate precautions, these can mainly be avoided. Minor effects include mild bruising, local pain, syncope, drowsiness, headache, and an atopic reaction. These can be minimized but are not always avoidable. However, with adequate explanation and informed consent, these minor adverse effects do not pose a problem when acupuncture is being used for an appropriate clinical indication.

12.2.1 Major Adverse Effects of Acupuncture

Major adverse effects are potentially life-threatening but quite rare. They are reduced by excellence in training and maintaining professional standards. The practitioner should recognize the worst case scenario when inserting needles or studs into specific acupuncture points. High risk situations and points that are more likely to result in complications should be avoided or the risks minimized by appropriate extra care. The patient should be warned of potential complications and asked to report relevant symptoms. Urgent referral to an emergency specialist for diagnosis and treatment must be made if a serious complication is suspected.

Major adverse effects of acupuncture (in order of frequency of reports, see Appendix for references):

- Pneumothorax
- Hepatitis, human immunodeficiency virus (HIV), and other blood-borne infections
- Retained needle, migrating needle and/or organ perforation
- Brain or spinal cord perforation (pith)
- Bacterial endocarditis
- Perichondritis
- Pericardial effusion or tamponade
- Septicemia
- Major hemorrhage
- Pseudoaneurysm/thromboplebitis
- Compartment syndrome
- Skin infection
- Abscess

Pneumothorax is the most common serious complication that is reported in the literature. Some cases occurred because a blanket was pulled over the patient and pushed the needle further in. Other cases occurred because of the patient falling with a needle in place after developing syncope. Rarely is the pneumothorax a result of direct deep penetration by a well-trained and experienced practitioner. Caution must be practiced for certain points, such as Jianjing (GB21), and horizontal shallow insertion should be used in this situation. In addition, patients with hyperinflated lungs (such as asthma and emphysema) or with thin chest walls (such as cancer cachexia) are at additional risk. Obviously, subjects should not be released with permanent insertions at these high-risk points and should not be doing self-acupuncture. A good practice would be to observe patients for 30 min after treatment, but this does not exclude the later development of a pneumothorax. An early pneumothorax can only be diagnosed with a chest X-ray. A puncture of the pleura can rapidly progress to a tension pneumothorax in which air becomes trapped in the pleural space and the rapidly escalating pressure prevents further inspiration and causes collapse of the cardiac output. At that point, urgent intervention with a chest drainage tube is required. Early suspicious signs can include a dry cough, dyspnoea and chest pain. These signs should indicate a medical emergency.

Perforation of an artery can result in a major hemorrhage. Dilated (varicose) veins can also bleed profusely. The situation is made worse by anticoagulants, inherited coagulation disorders, and platelet aggregating inhibitors (including aspirin). The patient should always have a full drug history taken as well as an inquiry into genetic disorders such as hemophilia. Cardiac tamponade is recorded in the literature. Ectopic sternal foramina may sometimes increase the subject's susceptibility to cardiac perforation. Bleeding into a cavity is usually accompanied by severe pain (pleural, pericardial, or peritoneal irritation) and an obtund patient. Bleeding into a muscle may present simply as an enlarging lump. Again, a high index of suspicion is required, with immediate referral as an emergency if this complication is suspected.

Organ perforation has also been reported with retained or broken needles. A needle count should always be carried out at insertion and removal. If the patient is sent home with semi-permanent studs, careful education of the subject is important, emphasizing that regular self-monitoring is essential. Avoidance of infection by good hygiene is imperative. High risk points must be avoided in these subjects.

The risk of infection is reduced by good hygiene, skin cleaning and the use of sterile needles. Greater caution must be exercised with immune-suppressed subjects. The needle should not be inserted through infected skin since the resultant bacteremia can lead to septicemia (infection of the blood), distant abscesses, and bacterial endocarditis. Staphylococcus poses a major risk of distant abscesses spread *via* the blood. Septicemia can result in shock, renal failure, and death. Needled contaminated skin can introduce “flesh eating disease” or necrotizing fasciitis, a particularly virulent form of group A streptococcal infection of the soft tissues.

The spread of infection through needle contamination with blood and other body fluids should be impossible when using sterile disposable needles. In fact it is law in some jurisdictions that the needles cannot be reused. All acupuncture needles must be sterilized, single use needles. That means that the needles are only used once and then disposed of. This prevents any spread of infections and ensures that every needle is clean and safe to use. It is important that the manufacturing standards and sterilization of these disposable needles are regulated by the importing jurisdiction. Of course, this does not prevent cross-infection from an accidental needle stick injury to the practitioner. It is important that precautions are taken to prevent this by care in needle insertion and removal, protecting the needle with a sheath, and using a sharps box for disposing of used needles. If a needle stick injury does occur, this should be documented, and both patient and practitioner should present for testing for hepatitis and HIV status, and possible prophylaxis. Practitioners should seriously consider hepatitis B vaccination prior to practicing acupuncture.

A needle placed near the craniocervical junction can result in perforation of the medulla oblongata. Pain can be local, in the head, or radiating into the trunk or limbs. A case is well described by Fukaya et al. (2011). The latter case was caused by a broken needle that migrated into the brainstem. The neck must be urgently immobilized to prevent further migration, and neurosurgical extraction carried out. Bleeding into the brainstem can result in sudden death.

Acupuncture in children will require special precautions, especially since the depth of insertion will be less than adults. The safe depth to which the 12 abdominal CV meridian acupoints can be needled was found to increase with age, body weight and waist girth in pediatric patients aged 7–15 years. Practitioners who perform acupuncture in pediatric patients should be aware of the large variations in the safe depth of acupoints to prevent possible complications (Chen et al. 2008).

Retained needles can result in organ perforation and fistulae. Ulloth and Jaines (2007) report a CSF fistula and spine-related headache that resulted after embedded acupuncture needles migrated into the lumbar spinal canal (Fig. 12.1). The patient had undergone a series of low-back acupuncture treatments, the most recent of which had been approximately 14 months prior to the onset of his headache. During his final acupuncture session, several acupuncture needles had been inadvertently driven into

Fig. 12.1 Lateral radiograph of the lumbar spine demonstrating three thin metallic objects (*arrows*) posterior to three lumbar vertebrae



the soft tissues of his lower back. The acupuncturist assured the patient that the retained needles were harmless. The patient underwent surgical removal of the retained needles located at L1, L2, and L3. The L3 needle was noted to have penetrated the lamina and was projecting into the spinal canal. A broken needle can damage tissue, perforate organs, and migrate into body cavities. It is important to check that each withdrawn needle is intact and that a fragment is not left behind. A broken needle may arise from poor quality manufacture, erosion between the shaft and the handle, strong muscle spasm or sudden movement of the patient, incorrect withdrawal of a stuck or bent needle, or the prolonged use of galvanic current. If, during insertion, a needle becomes bent, it should be withdrawn and replaced by another needle. Too much force should not be used when manipulating needles, especially during lifting and thrusting. The junction between the handle and the shaft is the part that is apt to break. Therefore, in inserting the needle, one quarter to one-third of the shaft should always be kept above the skin. If a needle breaks, the patient should be told to keep calm and not to move, so as to prevent the broken part of the needle from going deeper into the tissues. If a part of the broken needle is still above the skin, remove it with forceps. If it is at the same level as the skin, press around the site gently until the broken end is exposed, and then remove it with forceps. If it is completely under the skin, it is probably best to take the patient to an emergency department for surgical intervention. The limb or body part should be immobilized to prevent further

migration until emergency surgical treatment can be carried out. It is important not to make the damage worse.

12.2.2 Minor Adverse Effects of Acupuncture

Minor adverse effects are not life-threatening and are more common. Local pain is quite usual and is often described as Deqi in the TCM literature, and is thought to be a prerequisite of effectiveness. This should be differentiated from severe persistent pain, which could suggest a complication. Petechiae and local bruising are common, but can be minimized through avoiding the puncture of veins. A study in pediatric cancer patients revealed minimal complications in the setting of an academic cancer centre with highly trained and experienced acupuncturists (Ladas et al. 2010). This was a retrospective case series that provided descriptive data on the safety of acupuncture using Japanese J-type Seirin needles, with mild manual stimulation administered at 0.5-cun depth in patients with cancer with and without thrombocytopenia. Of 237 acupuncture sessions, 20%, 8% and 19% of the sessions were administered to patients with severe, moderate, and mild thrombocytopenia, respectively. No bleeding side effects were observed. The study suggests that acupuncture is safe even in the setting of platelet counts below 50,000/ μ L. Seirin needles are particularly sharp and may reduce tissue tearing.

Minor adverse effects of acupuncture (in order of frequency of reports, see Appendix for references):

- Dermatitis
- Pain (at site of insertion or beyond)
- Bruising
- Syncope
- Fatigue and/or drowsiness
- Cutaneous herpes
- Argyria pigmentation
- Worsening symptoms
- Headache
- Stiffness
- Agitation

After insertion, the practitioner may find it difficult to withdraw the needle. This is due to muscle spasm, rotation of the needle with too wide an amplitude, or rotation in only one direction causing the muscle fibers to tangle around and grip the shaft. The patient should be asked to relax. If the cause is excessive rotation in one direction, the condition will be relieved when the needle is rotated in the opposite direction. If the stuck needle is due to muscle spasm, it should be left in place for a while, and then withdrawn by rotating, or massaging around the point, or another needle inserted nearby which often relieves the grip on the needle. If the stuck needle is caused by the patient having changed position, the original posture should be resumed and the needle withdrawn.

Syncope is common, especially after the first treatment. Syncope during acupuncture treatment is a form of vasovagal syncope (also called neurally-mediated or neurocardiogenic syncope), which causes a sudden decrease in or brief cessation of cerebral flow caused by hypotension from inhibition of the sympathetic nervous system and activation of the parasympathetic nervous system (Chen et al. 1990; Abboud 1993). Acupuncture is known to modulate the sympathetic to parasympathetic activities and this is demonstrated by the technique of heart rate variability measurement (Alraek and Tan 2011). The patients often complain of not feeling well and/or fear of blackouts. This is followed by pallor, weakness, lightheadedness, yawning, nausea, diaphoresis, hyperventilation, and subsequently blurred vision. Despite recovering spontaneously in most cases, some patients may lose consciousness, especially if they are not managed immediately (Chen et al. 1990, Norheim and Fønnebo 1996). Convulsive syncope, characterized by irregular clonic-tonic movement, has been reported (Cole et al. 2002). The episode occurred immediately after the insertion of acupuncture needles into the bilateral ST36 acupuncture points. Causes could include oxygen depletion of the brain and/or afferent neurogenic-induced seizure. Transient hypoglycemia is another possibility. Needle phobia and anxiety have been documented as causes of actual syncope, as well as convulsive syncope. In one study, several subjects who experienced convulsive syncope while donating blood had previous histories of convulsive syncope during phlebotomy (Lin 1982). The possibility of needle anxiety in first time acupuncture patients should be anticipated and discussed with each subject. By orienting new patients to the acupuncture process and, in particular, by acquainting them with the needles themselves and the sensations they may produce, anxiety can be reduced or eliminated, thus lessening the risk of convulsive syncope during acupuncture. Convulsive syncope can result in secondary complications, such as a broken needle, organ perforation, pneumothorax, or moxa burns. If a patient becomes syncopal, ensure he is lying flat with his head below the level of his legs. Unless the patient has chronic bronchitis (risking suppression of ventilation from high dose oxygen), 40% oxygen inhalation may be given (ensuring there is no burning moxa around). Although syncope is most common and usually reversible without harm, chest pain and/or shortness of breath could suggest a myocardial infarction, pneumothorax or cardiac tamponade. Persistent unconsciousness or convulsions could suggest hypoglycemia or a cerebrovascular event. The practitioner should carefully attend to the patient's past medical history (including cardiopulmonary disease, type 1 diabetes mellitus and primary seizures), as well as noting the needle insertion points. Measurement of blood pressure (lying flat) and the checking of pulse rate and heart rhythm and determining whether the patient is cyanosed should be done and recorded. This should help to discriminate a straight forward syncope (from which the patient will recover in the recumbent position) from other more serious disorders requiring urgent medical attention. A vasovagal syncope is usually manifest by a slow regular pulse, pale skin color, and hypotension that recover when the subject lies flat. If warning symptoms appear, remove the needles immediately and make the patient lie flat with his head down and his legs raised, since the symptoms are probably due to a transient, insufficient blood supply to the brain. Offer warm sweet drinks. The symptoms usually

disappear after a short rest. In severe cases, first aid should be given and, when the patient is medically stable, the most appropriate of the following treatments may be applied: Press or acupuncture Shuigou (GV26), Zhongchong (PC9), Suliao (GV25), Neiguan (PC6) and ST36. If the symptoms persist, emergency medical assistance will be necessary.

Drowsiness may also occur. The sleepiness can be due to release of serotonin and endorphins in the brain and systemically (Yoshimoto et al. 2006, Han 2004). Patients should be warned about driving and operating machinery for a few hours if they should develop these symptoms. Relaxation of muscles can increase the risk of musculoskeletal or neurological injury at an injured site if patients are not warned to be cautious. Observation during and after the first session and charting the patient's symptoms will help to reduce mishaps in future sessions.

12.3 Adverse Effects of Moxibustion

Adverse effects of moxibustion are summarized below (in order of frequency of reports, see Appendix for references):

- Burns
- Scarring
- Allergic reactions
- Respiratory symptoms.

Moxibustion has several kinds of potential adverse events such as allergy, burns and infection. Currently, the incidence of such events is not really known, which may be because it is widely used in Asia (where adverse events reporting has been rare until recently), but to the best of our knowledge, is not used so much in N. America and Europe in medical clinics. A Japanese audit of 65,000 treatments of both acupuncture and moxibustion revealed seven burn injuries of which one deep burn took 2 years to recover. Five cases were indirect burns from a moxa stick, one was from an infra red lamp, and the other from a hot pack (Yamashita et al. 1999). A systematic review revealed the most common effects were allergic reactions, burns, and infections such as cellulitis and hepatitis C (Park et al. 2010). Allergic reactions were reported in six case reports (four case reports related to infections and two related to burns). The other articles from this systematic review included case reports of xerophthalmia, xeroderma, hyperpigmented macules, ptosis and eversion of the eyelids. In clinical trials, various adverse events such as rubefaction, blistering, itching sensations, discomfort due to smoke, general fatigue, stomach upsets, flare-ups, headaches, and burns have been reported. The odor may be deemed unpleasant and cause nausea and dry throat and breathing problems. Other adverse effects have included abdominal pain, premature birth, premature rupture of the membrane and bleeding due to excess pressure from moxa trays on an anterior placenta in pregnant women.

In Chinese medicine, the main contraindication for moxibustion is the presence of a heat syndrome. Theoretically, it could cause the disease to worsen.

Moxa is considered inappropriate for a deficiency heat syndrome (one based on yin deficiency) and it must be used cautiously in cases where there is local dryness. Other contraindications for moxibustion involve the sensitive areas of the body, such as the face (due to potential risks of scarring from burns, and also because the smoke can irritate the eyes or nose), the nipples, and the genitals. Ancient texts specify certain points on the head as being contraindicated for moxibustion, such as Shangxing (GV23), Chengqi (ST1), Sibai (ST2), Touwei (ST8), Jingming (BL1), Cuanzhu (BL2), Sizhukong (TB23), Heliao (LI19) and Yingxiang (LI20). Concerns have also been raised for using moxa during pregnancy in the region of the abdomen and lower back (O'Connor and Bensky 1981).

12.4 Precautions and Guidelines

Risks, precautions and guidelines to prevent complications are summarized below:

12.4.1 Risk Factors for Complications

1. Inadequate training
2. Bleeding
 - a. Hemophilia and other coagulation disorders
 - b. Extreme thrombocytopenia ($<20,000/\mu\text{L}$)
 - c. Advanced liver disease reduces clotting factors
 - d. Anticoagulants and anti-platelet drugs
3. Infection
 - a. Immunocompromised patients
 - i. High dose steroids
 - ii. Transplant immunosuppression
 - iii. HIV
 - iv. Chronic lymphocytic leukemia
 - b. Diabetics
 - c. Open wounds
 - d. Cardiac valve abnormalities
4. Fainting
 - a. Hypoglycemia
 - b. Anxiety
 - c. Vasovagal sensitivity

12.4.2 Precautions

1. Avoid directly needling the tumor.
2. Avoid deep perpendicular penetration of points on thoracic and lumbar regions due to risk of perforating internal organs.
3. Avoid deep penetration of points at base of skull inferior to the occiput, in order to reduce risk of perforation of the brainstem (points at risk: Fengchi (GB20); Fengfu (GV16); Tainzhu (BL10)).
4. Avoid deep penetration of Naohu (GV17), to reduce risk of cardiac tamponade.
5. Use extreme caution with GB21, since this risks pneumothorax.
6. Avoid deep and perpendicular penetration over a full stomach or bladder.
7. Points close to the orbit require experience and skill in angling the needle and delivering the correct depth of penetration (ST1, Tongziliao (GB1), BL1). Do not manipulate needle.
8. Avoid points on scalp in infants with open fontanelles.
9. Avoid points in pregnant women that can induce labor (Hegu (LI4), Sanyinjiao (SP6), Kunlun (BL60), Zhiyin (BL67)).

12.4.3 Guidelines: Acupuncture for Cancer Patients (with Permission and Acknowledgments, Filshie and Hester 2006)

12.4.3.1 Roles and Responsibilities

It is the responsibility of the doctor/practitioner in charge of the service to ensure that:

- a. Doctors receive appropriate training to practice acupuncture safely and competently.
- b. Allied health professionals are appropriately trained to practice acupuncture safely and competently.
- c. Doctors and nurses and other allied health professionals are aware of the hospital or clinic's policies and guidelines for the safe practice and treatment of patients receiving acupuncture.

12.4.3.2 Criteria for Acupuncture Practice

- a. Training and competence.
- b. Regulated health professionals who practice acupuncture will commence treatment only after an orthodox medical diagnosis which comprises history, examination and any further investigations as necessary.
- c. They must be aware of the diagnosis and stage of cancer in a given patient.

- d. All acupuncturists should be a member of a regulated health care professional body and comply with their standards and codes of conduct. Regulation will vary according to the practitioner's primary specialty. For example, a practitioner would be registered under a legislated college or council for general medicine. Regulation may also be mandatory for primary acupuncturists. For example, some states in the USA require registration by a body that is recognized by the Federation of Acupuncture and Oriental Medicine Regulatory Agencies. Similar regulations apply to some provinces within Canada. The practitioners should receive training from an accredited school to a level specified by the regulatory body. In the USA, they should have attended an ACCAOM accredited school and passed the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) examination. Practitioners should also be trained by appropriate institutions, such as schools recognized by the American Association of Medical Acupuncture, the British Medical Acupuncture Society, or the Acupuncture Foundation of Canada.

12.4.3.3 Patients Who Should Be Considered for Acupuncture

- a. Patients who fail to respond to conventional analgesic approaches and remain in pain.
- b. Patients who experience unacceptable side effects with conventional medication such as excessive sedation.
- c. Patients who wish to reduce existing medication.
- d. Patients who have pain that is likely to respond to acupuncture.
- e. Patients who do not wish to have conventional analgesia or other medications for symptom control.

12.4.3.4 Contraindications and Cautions

- a. Contraindicated
 - i. Needle phobia
 - ii. Severe clotting dysfunction or platelets less than 20,000/ μ L
 - iii. Semi-permanent needles (studs) in patients with vascular heart disease (risk of sub-acute bacterial endocarditis) or neutropenic patients or post-splenectomy (risk of infection)
 - iv. Electroacupuncture in patients with an intracardiac defibrillator
 - v. No needling a tumor nodule or area of ulceration
 - vi. Avoid lymphoedematous limbs
 - vii. Mainly avoid a limb that has received a groin or axillary node dissection (increased risk of infection and further obliteration of lymphatic vessels)
 - viii. Regions of spinal instability (potential for cord or root compression due to acupuncture's muscle-relaxing properties)

- ix. Into a breast prosthesis (leading to leakage)
 - x. Over intracranial skull or vertebral deficits, following neuro-surgery (could inadvertently penetrate spinal cord or brain)
- b. Cautions
- i. Patient may be very sensitive to acupuncture, especially the vaso-vagal response and drowsiness. Patient should be observed after initial treatments and warned not to drive. Syncope after initial treatments is quite common.
 - ii. Extreme care not to needle too deeply over the chest wall, especially in cachectic patients (to avoid pneumothorax).
 - iii. Patients prone to keloid
 - iv. Pregnancy
 - v. Epilepsy
 - vi. Confused patients
 - vii. Electroacupuncture if pacemaker present

12.4.3.5 Acupuncture Treatment

- a. Pre-treatment
- i. Critically decide whether the patient is suitable for acupuncture.
 - ii. Discuss the use of acupuncture, its relative effectiveness, and potential risk of adverse effects, including post-treatment drowsiness, the possibility of exacerbation of symptoms and minor bruising or pain at needle sites.
 - iii. Obtain the patient's verbal (or written) consent.
- b. Acupuncture equipment and handling
- i. Use single use disposable needles and clean skin at site of insertion.
 - ii. After insertion, the introducers will be counted twice and the number recorded, and/or the needles are counted.
 - iii. When the needles are removed, they will be counted twice and formally checked against the earlier record that the same number are removed as inserted.
 - iv. Used needles will be disposed of directly into a sharps box.
- c. First treatment
- i. Patients should be treated lying down in case of vaso-vagal reactions; initial treatment should be gentle.
 - ii. The patient should be observed during first treatment.
 - iii. The patient should be followed up at least once per week to gauge response and adverse effects. Usually six treatments is considered an adequate clinical trial.

12.4.3.6 Audit

- a. Adverse effects should be carefully documented along with treatment response.
- b. Unexpected adverse effects should be reviewed by clinical teams and efforts made to reduce these as far as possible.

They are further discussed by Cummings and Reid (2004). Electrical stimulation is potentially harmful. It is contraindicated: in pregnancy; if the patient has a pace-maker; if there is lack of skin sensation; and in cases of impaired circulation, severe arterial disease, undiagnosed fever or severe skin lesions. Careful monitoring of the electrical stimulation is recommended to prevent neural injury. Galvanic current should be used for only a very short period of time.

12.4.4 Guidelines for Moxibustion in Cancer Patients

Acupoints to be avoided or those requiring special skill are listed below:

1. Explain the slight risks of burns and obtain informed consent.
2. Do not leave the patient alone with burning moxa.
3. Contraindications for moxibustion involve the sensitive areas of the body, such as the face (due to potential risks of scarring from burns, and also because the smoke can irritate the the eyes or nose), the nipples, and the genitals. Ancient texts specify certain points on the head as being contraindicated for moxibustion, such as GV23, ST1, ST2, ST8, BL1, BL2, TB23, LI19, and LI20.
4. To avoid the smoke of regular moxibustion, use other methods of heating that allow constant heat output and control over the heat. These can include smokeless moxa or an infra red heat lamp. In many situations, acupuncture can replace moxa.
5. When using herb-slice or cake interposed moxibustion, punch holes in the material to allow the heat to penetrate. The thickness of the slice should be just 0.2–0.3 cm; thicker slices may prevent adequate heating. For practical purposes, ginger slices may be most convenient.
6. For an effective moxibustion, it should cause significant local heating and an inflammatory response, and should be done for a prolonged period, such as 10–20 min. Specific points for moxa heating should be selected from TCM theory to stimulate the immune system or to alter internal organ functions. Warming a broader region is an acceptable treatment for relaxing tension and moderating pain at the site. Chinese medicine practitioners typically administer moxa daily for several treatments or more. They may be alternated with acupuncture.
7. The most frequently mentioned applications of moxa are for cancer, gastro-intestinal disorders, asthma, breech pregnancy, organ prolapse, bi-syndromes, and herpes zoster. In particular, herpes zoster is emphasized as a case where moxibustion is effective.
8. The risks of exposure to moxa smoke are probably similar to that for any other smoke, and total exposure time, particularly when it involves prolonged exposure,

is the key concern. Venting or filtering the room is important when moxa is done regularly. There is no evidence that moxa smoke contains any unusually harmful substances, but the long-term outcome data are incomplete. Standard commercial moxa materials do not contain arsenic, but this toxic substance is found in some preparations from China and should be avoided.

9. Specific acupoints are relatively convenient to treat with moxa, and are well accepted by most patients. Most of the points are on the conception and governing vessels, plus ST36 and Yongquan (KI1), and the Shu points on the back.

Although female patients are unlikely to be pregnant during anti-cancer treatment, they may well become pregnant during follow up. In those cases, certain acupuncture points can result in uterine contractions and should be avoided.

12.4.5 Acupoints to Be Avoided or Only Used by Experienced Specialists for Both Acupuncture and Moxibustion

Contraindicated acupuncture points are summarized below:

1. Risk of neurological damage:
 - Yamen (GV15), GV16, may puncture medulla oblongata
2. Risk of organ damage:
 - BL1, ST1, located close to the eyeball
 - Tiantu (CV22), in front of the trachea
 - Renying (ST9), near the carotid artery
 - Jimen (SP11), Chongmen (SP12), near the femoral artery
 - Taiyuan (LU9), on the radial artery
 - GB21, apply caution in thin patients, to prevent pneumothorax
 - Avoid if pregnant
 - First trimester: points on lower abdomen and lumbosacral region
 - Second trimester onwards: upper abdomen and lumbosacral
 - Throughout pregnancy: strong sensation points, ear acupuncture labor points, SP6, LI4

Further guidelines on acupuncture and moxibustion safety have been issued by the World Health Organization (WHO 1999).

12.5 Conclusion

The rate of complications is very low and most complications are transient, lasting 2 weeks at most. Adverse effects occur in 10–15% of patients and are usually quite minor and do not deter patients from further treatment. Major adverse effects, that can be life-threatening, occur in less than 0.3% of treatments. Practitioners must be

well aware of potentially fatal progression when patients report shortness of breath, pleuritic chest pain, severe bruising, an enlarging tissue mass, abdominal and chest pain, persistent syncope, or a fever after receiving acupuncture treatment. A third degree burn from moxibustion can result in severe infection and non-healing. All of these situations require urgent referral to an appropriate specialist.

The conclusion that acupuncture is a very safe intervention in the hands of a competent practitioner is justified on the evidence available (Leung and Zhang 2008). In considering the dangers of orthodox treatments, the proven efficacy of the optional treatments must be considered. Clinical trials in Chinese medicine have improved and there is some encouraging evidence that acupuncture is effective for many chronic conditions and in the supportive care of cancer patients (Sagar 2008; Wong and Sagar 2010). The considerable risks of hospital treatment are becoming more apparent, along with the rates of adverse drug reactions or prescribing errors. Whereas the risks of acupuncture cannot be discounted, it seems that in skilled hands it is one of the safer forms of medical intervention. The balance of risk and benefit is the key for patients and for those regulating or funding health care. Importantly, the surveys and reports of adverse events for acupuncture and moxibustion represent an effort by acupuncture practitioners to address the issue of patient safety. As with all medical interventions, it is important to continuously evaluate efficacy, risks, likely mechanisms, acceptability, and cost effectiveness (Vincent 2001).

Acknowledgments Joel E. Ulloth and Stephen J. Haines, Department of Neurosurgery, University of Minnesota, Minneapolis, Minnesota, USA (Ulloth and Haines 2007).

Appendix

Table 12.1 References for major adverse effects of acupuncture

| Adverse effect | Reports |
|--|---|
| Major hemorrhage | Sakaguchi and Nishimura 1990; Keane et al. 1993; Choo and Yu 2000 |
| Septicemia | Pierik 1982; Carron et al. 1974; Doutsou et al. 1986; Izatt and Fairman 1977 |
| Skin infection | MacPherson et al. 2004 |
| Abscess | Garcia and Venkataramani 1994 |
| Bacterial endocarditis | Cheng 1983; Cheng et al. 1985; Jeffreys et al. 1983; Lee and McIlwain 1985; Scheel et al. 1992 |
| Retained needle, migrating needle and/or organ perforation | Benscholen 1986; Southworth and Hartwig 1990; Chiu and Austin 1995; Keller et al. 1972; Yuzawa et al. 1991; Abumi et al. 1996; Hama and Kaji 2004; Miyamoto et al. 2010; MacPherson et al. 2004 |
| Brain or spinal cord perforation (pith) | Isu et al. 1985; Kida et al. 1988; Kishikawa et al. 1990; Abumi et al. 1996; Gi et al. 1994; Kondo et al. 1979; Sasaki et al. 1984; Shiraishi et al. 1979; Fukaya et al. 2011 |
| Pneumothorax | Gray et al. 1991; Stack 1975; Wright et al. 1991; Hasegawa et al. 1991; Bodner et al. 1983; Corbett and Sinclair 1974; Goldberg 1973; Lewis-Driver 1973; Ritter and Tarala 1978; Valenta and Hengesh 1980; Waldman 1974; Gee 1984; Kuiper 1974; Mazal et al. 1980; Vilke and Wulfert 1997; Carette et al. 1984; Olusanya and Mansuri 1997; Carron et al. 1974; Guerin et al. 1987; Henneghien et al. 1984; Huet et al. 1990; Kropp and Hasler 1983; Morrone et al. 1990; Schneider and Salzberg 1984; Takishma 1983 |
| Hepatitis, human immunodeficiency virus and other blood-borne infections | Alexander et al. 1974; Conn 1988; Kent et al. 1988; Kiyosawa et al. 1987; Phoon et al. 1988; Slater et al. 1988; Stryker et al. 1986; Vittecoq et al. 1989; Castro et al. 1988; Boxall 1978; Hussain 1974; Shimoyama et al. 1993 |
| Perichondritis | Allison and Kravitz 1975; Davis and Powell 1985; Warwick-Brown and Richards 1986 |
| Pericardial effusion or tamponade | Cheng 1991; Halverson et al. 1995; Hasegawa et al. 1991; Kataoka 1997; Nieda et al. 1973 |
| Compartment syndrome | Smith and Walzcyk 1986 |
| Psuedoaneurysm/thrombophlebitis | Fujiwara et al. 1994; Lord and Schwarz 1996; Blanchard 1991 |

Table 12.2 References for minor adverse effects of acupuncture

| Adverse effect | Reports |
|---------------------------------------|---|
| Petechiae/bruising | MacPherson et al. 2004 |
| Dermatitis | Castelain et al. 1987; Dung 1987; Koizumi et al. 1988; Newman 1990; Buchta 1972 |
| Cutaneous herpes | Chang 1974 |
| Pain (at site of insertion or beyond) | Lapeer 1988; MacPherson et al. 2004 |
| Argyria pigmentation | Tanita et al. 1985 |
| Syncope | Zhenlong 1992; MacPherson et al. 2004 |
| Fatigue and/or drowsiness | MacPherson et al. 2004 |
| Worsening symptoms | MacPherson et al. 2004 |
| Headache | MacPherson et al. 2004 |
| Stiffness | MacPherson et al. 2004 |
| Agitation | MacPherson et al. 2004 |

Table 12.3 References for adverse effects of moxibustion

| Adverse effect | Reports |
|--------------------|---|
| Scarring | Hung and Mines 1991; Park et al. 2010 |
| Burns | MacPherson et al. 2004; Park et al. 2010; Yamashita et al. 1999 |
| Allergic reactions | Park et al. 2010 |
| Respiratory | Park et al. 2010 |

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